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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,521	11/01/2005	Paolo Villoresti	TOR0106	8971
832 7590 05/08/2008 BAKER & DANIELS LLP 111 E. WAYNE STREET SUITE 800 FORT WAYNE, IN 46802				
EXAMINER				
BASHAW, HEIDI M				
ART UNIT		PAPER NUMBER		
3732				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/533,521

Applicant(s)

VILLORESI ET AL.

Examiner

HEIDI M. BASHAW

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-13 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 03 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-85/86)
Paper No(s)/Mail Date 5/3/2005
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the limitation "the optical fiber" in 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-6, 8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. 5,435,724 (Goodman) in view of Kowalyk et al. 5,456,603 (Kowalyk).
3. Re claim 1, Goodman teaches a method for treating hard tissues comprising the steps of generating a radiation from a diode laser (col. 5, ll. 21-24), which is a type of semiconductor laser source, focusing the radiation on the surface of the tissue by means of an adapted optical system and exceeding a fluence threshold of the laser radiation as a function of the tissue to be treated (col. 4, ll. 38-51, 65-68).

4. Goodman does not teach applying a chromophorous agent with high absorption at the wavelength of the laser to a region of a tissue to be treated so as to have predominant absorption at a surface of the tissue.
5. Kowalyk teaches applying a chromophorous agent with high absorption at the wavelength of the laser to a region of a tissue to be treated so as to have predominant absorption at a surface of the tissue (col. 4, ll. 64-67, col. 5, ll. 1-2).
6. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify Goodman in view of Kowalyk in order to help protect the healthy portions of the tissue as taught by Kowalyk (col. 5, ll. 2-5).
7. Re claim 3, Goodman teaches the method characterized in that the duration of the pulse is comprised between 10 and 50,000 μ s (col. 8, ll.28-29).
8. Re claim 4, Goodman teaches the method characterized in that the laser radiation is conveyed by means of a guided optical system (col. 4, ll. 65-67).
9. Re claim 5, Goodman teaches the method characterized in that the guided optical system is an optical fiber (col. 5, ll. 1-5).
10. Re claim 6, Goodman teaches the method characterized in that the focusing of the radiation in output form the optical fiber on the surface of the tissue is achieved by means of a system of lenses or mirrors (col. 4, ll. 65-68).
11. Re claim 8, Goodman teaches an apparatus for treating hard tissues comprising a source of laser light that contains at least one diode laser (col. 5, ll. 21-24), which is a type of semiconductor laser source, an optical system for focusing the last light on the

surface to be treated, characterized in that the fluence threshold of the generated laser radiation is variable (col. 4, ll. 38-51, 65-68).

12. Goodman does not teach the apparatus comprising a system for applying a chromophorous agent to the surface of a tissue.

13. Kowalyk teaches the apparatus comprising a system for applying a chromophorous agent to the surface of a tissue (col. 4, ll. 64-67, col. 5, ll. 1-2).

14. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify Goodman in view of Kowalyk in order to help protect the healthy portions of the tissue as taught by Kowalyk (col. 5, ll. 2-5).

15. Re claim 10, Goodman teaches the apparatus characterized in that the duration of the pulse is comprised between 10 and 50,000 μs (col. 8, ll. 28-29).

16. Re claim 11, Goodman teaches the apparatus characterized in that the laser radiation is conveyed by means of a guided optical system (col. 4, ll. 65-67).

17. Re claim 12, Goodman teaches the apparatus characterized in that the guided optical system is an optical fiber (col. 5, ll. 1-5).

18. Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. 5,435,724 (Goodman) in view of Kowalyk et al. 5,456,603 (Kowalyk) as applied to claims 1 and 8 above, and further in view of Neev 6,156,303.

19. Re claims 2 and 9, Goodman in view of Kowalyk does not teach the method or apparatus characterized in that the fluence threshold of the laser radiation is between 20 and 100 J/cm^2 .

20. Neev teaches the fluence threshold of the laser radiation is between 20 and 100 J/cm² (col. 9, ll. 1-4).

21. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify Goodman in view of Kowalyk further in view of Neev since it has been held that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." (*In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) MPEP 2144.05 II A).

22. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. 5,435,724 (Goodman) in view of Kowalyk et al. 5,456,603 (Kowalyk) as applied to claim 1 above, and further in view of Summers et al. 5,611,690 (Summers).

23. Re claim 7, Goodman in view of Kowalyk does not teach the method characterized in that the chromophorous agent is sprayed onto the tissue by means of an aerosol.

24. Summers teaches a method of spraying an agent onto the tissue by means of an aerosol (see abstract).

25. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify Goodman in view of Kowalyk further in view of Summers in order to make applying the agent to the tissue more convenient for the user.

26. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. 5,435,724 (Goodman) in view of Kowalyk et al. 5,456,603 (Kowalyk) as applied to claim 8 and 11-12 above, and further in view of Myers 6,019,605.

27. Re claim 13, Goodman in view of Kowalyk does not teach the apparatus characterized in that the optical fiber has a diameter from 5 to 2000 μm .
28. Myers teaches the apparatus characterized in that the optical fiber has a diameter from 300 to 600 μm (col. 2, ll. 33-36).
29. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify Goodman in view of Kowalyk further in view of Myers since it has been held that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." (*In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) MPEP 2144.05 II A).

Conclusion

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HEIDI M. BASHAW whose telephone number is (571)270-3081. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on 571-272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Heidi Bashaw
Examiner
Art Unit 3732

/John J Wilson/
Primary Examiner
Art Unit 3732

HMB